In accordance with the requirements of 37 C.F.R. § 1.121, the attached Appendix shows the changes that have been made by this amendment.

REMARKS

I. Status of the Application and Claims

With entry of this amendment, claims 19-81 are pending in the application. All claims have been rejected. Support for the amendments are found in the original specification as-filed and in all priority applications. For example, support for claims 54 and 55 is found in the original as-filed specification in claim 14. Claims 30, 61, 69, and 79 have been amended to delete one member of the recited group, "myristyl alcohol," to ensure that all the fatty alcohols recited in the claims are liquid fatty alcohols. The amendments introduce no new matter.

II. Enablement Rejection of Claims 71-85

The Office rejected claims 71-85[1] "under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for method of treating hair, does not reasonably provide enablement for method of '*protecting keratinous materials from physical and chemical attacks*'." Office Action, page 2. The Office alleges that '[t]he burden of enabling the protection from physical or chemical attacks as claimed (i.e., the need for additional testing) would be greater than that of enabling a treatment due to the need to screen the keratinous materials susceptible to such conditions." *Id.* Applicants traverse this rejection.

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[1] Applicants note that only claims 19-81 are pending in the application at this time. It is therefore presumed that the Examiner intended to reject claims 71-81.

Regarding claims 71-73, it appears the Office has erroneously included these claims in the enablement rejection because claims 71-73 do not recite "protecting ...from physical and chemical attacks." Applicants respectfully request reconsideration and withdrawal of the rejection regarding claims 71-73.

Regarding claims 74-81, Applicants disagree with the Office for the following reasons. First, the overall "test of enablement" is whether one reasonably skilled in the art could make or use the invention from the disclosure in the patent application coupled with information known in the art without undue experimentation. *See* M.P.E.P. 2164.01. With regard to this application, the disclosure details the methods of treating keratinous materials that are appropriate for the invention, and also includes information that is known in the art about treating keratinous materials. *See*, e.g., the specification at page 16, lines 4-26. Based upon this disclosure and the knowledge of one skilled in the art Applicants submit that the specification enables methods of using the claimed invention for protecting keratinous materials from physical and chemical attacks without undue experimentation.

Second, according to M.P.E.P. § 2164.04, the Office has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. The Office may do so by making specific findings of fact, supported by evidence, and then drawing conclusions based on these findings of fact. As stated in M.P.E.P. § 2164.01, there are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any experimentation is "undue." These factors, known as the *Wands* factors, include, but are not limited to: (1) the breadth of the claims; (2) the nature of the invention; (3) the state of the prior

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art; (4) the level of ordinary skill; (5) the level of predictability in the art; (6) the amount of direction provided by the inventor; (7) the existence of working examples; and (8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. M.P.E.P. § 2164.01(a), citing *In re Wands*, 858 F.2d 731, 737 (Fed. Cir 1988)). In evaluating these *Wands* factors, the Office's analysis must consider all the evidence related to each one of these factors, and any conclusion of nonenablement must be based on the evidence as a whole.

The outstanding Office Action contains no such evaluation of the *Wands* factors. If the Office, as required, applied and weighed the *Wands* factors, Applicants submit the Office must conclude that the present disclosure sufficiently enables one of ordinary skill to practice the claimed invention. In other words, after the Office evaluates each of the *Wands* factors above as applied to the claims as a whole, sufficient guidance for one of skill in the relevant art to prepare and use the claimed compositions without undue experimentation will be found.

Applicants therefore respectfully request reconsideration and withdrawal of the rejection.

III. Indefiniteness Rejection of Claim 55

The Office rejected claim 55 under 35 U.S.C. § 112, second paragraph, as being indefinite because "[t]he expression 'a C16-C40 fatty acid chosen from 18-methyleicosanoic acid, hydroxy acids, vitamins, panthenol and fatty esters' is vague and confusing, and such fatty acids in the claim limitation lack the support from the specification." Office Action at page 3.

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Applicants disagree with the rejection. In order to promote the prosecution of the application, however, Applicants hereby amend claims 54 and 55 solely to more particularly describe the subject matter of the invention. Support for the amended claims is found, for example, in the original as-filed specification in claim 14. No new matter has been added.

Applicants respectfully request reconsideration and withdrawal of the rejection.

IV. Rejections under 35 U.S.C. § 102

The Office rejected claims 19, 20, 57, 58, 62, 64, 65, 70, 74, 75, and 80 under 35 U.S.C. § 102(a), (b), and (e) as being anticipated by *Bergmann et al.*, U.S. Patent No. 6,110,450 ("*Bergmann*"), and rejected claims 19, 20, 52, 54, 56, 57, 58, 62, 64, 65, 70, 74, 75, and 80 under 35 U.S.C. § 102(a), (b), and (e) as being anticipated by *Dubief et al.*, U.S. Patent No. 5,679,357 ("*Dubief-A*"). (Office Action, pages 4-5.) Applicants traverse the rejections because *Bergmann* and *Dubief-A* do not teach all the limitations of the instant claims.

Bergmann

The Office asserts that *Bergmann* anticipates the instant claims because *Bergmann* allegedly discloses hair care compositions comprising ceramide, cationic surfactant, and fatty alcohols in a cosmetically acceptable medium. *Id.*, page 4. In order for a cited reference to anticipate a claimed invention, the reference must teach all of the limitations of the claims in question. M.P.E.P. § 2131.

Applicants point out that *Bergmann* does not anticipate the claimed invention because *Bergmann* does not disclose "liquid fatty alcohols", while each claim of the present invention requires "at least one **liquid** fatty alcohol." Independent claims 19,

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57, 64, and 74, emphasis added. The specification clearly describes the present invention as comprising a liquid fatty alcohol, and that the compositions comprising the liquid fatty alcohol "are superior to those" comprising "a solid fatty alcohol generally used for improving the stability of the compositions." Specification, page 2, lines 10-23. The specification then defines liquid fatty alcohols of the present invention as those that are liquid at a temperature of less than 30°C. Specification, page 8, lines 20-21.

Bergmann only discloses cetyl alcohol and stearyl alcohol as fatty alcohols (Example 2, components 5 and 6.) It is well known in the art, however, that the melting temperatures of cetyl and stearyl alcohol are 49-50°C and 57-58°C, respectively. (Convenience copies of a Chemical Supplier's descriptions for each are enclosed.) Therefore, cetyl and stearyl alcohols are not liquid fatty alcohols as defined by the present application. The Office has not provided any evidence that *Bergmann* discloses a liquid cosmetic composition, comprising, in a cosmetically acceptable medium, at least one **liquid** fatty alcohol, at least one ceramide compound, and at least one cationic surfactant. Accordingly, *Bergmann* does not anticipate the claimed invention because it does not teach all of the limitations of the instant claims. Applicants respectfully request reconsideration and withdrawal of the rejection.

In addition, Applicants point out that the claims were erroneously rejected over *Bergmann* under 35 U.S.C.§ 102(b) because *Bergmann*, which issued on August 29, 2000, was not patented more than one year prior to the filing date of this application, June 28, 2001.

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Dubief-A

The Office asserts that *Dubief-A* anticipates the instant claims because *Dubief-A* allegedly discloses hair care compositions comprising ceramide, cationic surfactant, and fatty alcohols in aqueous medium. Office Action, pages 4-5. Applicants point out that *Dubief-A*, similar to *Bergmann*, does not anticipate the claimed invention because *Dubief-A* does not disclose "liquid fatty alcohols", while each claim of the present invention requires "at least one **liquid** fatty alcohol."

Dubief-A only discloses cetyl alcohol and stearyl alcohol as fatty alcohols (Example 4). As discussed above, cetyl and stearyl alcohols are solid fatty alcohols, and are not liquid fatty alcohols as defined by the present application. The Office has not provided any evidence that *Dubief-A* discloses a liquid cosmetic composition, comprising, in a cosmetically acceptable medium, at least one **liquid** fatty alcohol, at least one ceramide compound, and at least one cationic surfactant. Accordingly, *Dubief-A* does not anticipate the claimed invention because it does not teach all of the limitations of the instant claims. Applicants respectfully request reconsideration and withdrawal of the rejection.

V. Rejections under 35 U.S.C. § 103(a)

Maubru* in view of *Bergmann* and *Dubief-B

The Office rejected claims 19-29 and 32-81 under 35 USC§ 103(a) as being obvious over *Maubru* (U.S. Patent No. 6,312,674 B1) ("*Maubru*") in view of *Bergmann* and *Dubief* (U.S. Patent No. 6,120,757) ("*Dubief-B*") for the reasons set forth on pages 6-8 of the Office Action. Applicants respectfully traverse the rejection.

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To establish a prima facie case of obviousness, an Examiner must meet three basic criteria, including that, the prior art reference must teach or suggest all the claim limitations, and (2) that there must be some motivation to combine the references, other than from the Applicants' own specification. See M.P.E.P. § 2143. In the present case, the Examiner has failed to make a prima facie case of obviousness because at least these two criteria have not been met.

As argued above, *Bergmann* does not disclose **liquid** fatty alcohols, and this argument is herein incorporated by reference. Similarly, the Office has not provided any evidence that *Dubief-B* discloses **liquid** fatty alcohols, and admits that *Maubru* fails to teach fatty alcohols of the instant claims. Office Action, page 7. Thus, Applicants submit that this argument also applies to *Maubru* in view of *Bergmann* and *Dubief-B* since, in combination, these references do not teach or suggest a composition comprising **liquid** fatty alcohols.

Furthermore, since the compositions of the cited references, either alone or in combination, lack a liquid fatty alcohol, there would therefore have been no motivation to make the Examiner's suggested combination to arrive at the compositions and methods of the present invention that comprise a liquid cosmetic composition, comprising, in a cosmetically acceptable medium, at least one **liquid** fatty alcohol, at least one ceramide compound, and at least one cationic surfactant. Applicants respectfully request that the rejection be reconsidered and withdrawn.

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Maubru* in view of *Bergmann*, *Dubief-B*, and *Critchley

The Office rejected claims 30 and 31 under 35 USC § 103(a) as being obvious over *Maubru* in view of *Bergmann*, *Dubief-B*, and *Critchley* (U.S. Patent No. 5,198,210) ("*Critchley*") for the reasons set forth on pages 8-9 of the Office Action. Applicants respectfully traverse the rejection.

The Office alleges that it would have been obvious "to have modified the compositions of [*Dubief-B*] by substituting the stearyl alcohol and cetyl alcohol with isocetyl alcohol, as suggested by Critchley, because of the expectation of successfully producing hair care products with similar emolliency effects." Office Action, page 9. Applicants respectfully submit that this argument lacks the required motivation and expectation of success and fails to meet the Office's burden of establishing a prima facie case of obviousness.

Critchley teaches a composition comprising a pseudoceramide and a cosmetically acceptable vehicle. Moreover, *Critchley* teaches wide variety of compounds that are useful as cosmetically acceptable vehicles "to act as a dilutant, dispersant or carrier for the pseudoceramide in the composition, so as to facilitate its distribution when the composition is applied to the skin and/or hair." Col. 10, lines 32-38. These cosmetically acceptable vehicles are further defined to include any of a multitude of liquid or solid emollients, propellants, solvents, humectants, thickeners, and powders. Col. 10, line 39, to Col. 11, line 11. A few liquid fatty alcohols are included amongst the long list of numerous emollients indicated, which also included numerous solid fatty alcohols and other non-alcoholic emollients. Thus, a vast majority of the emollients disclosed in *Critchley* would not be a liquid fatty alcohol.

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The Federal Circuit requires evidence of a suggestion or motivation to modify the teachings of prior art references. See, *e.g.*, *In re Dembiczak*, 50 USPQ.2d 1614 (Fed. Cir. 1999). Modifying prior art references without evidence of such a suggestion or motivation simply takes the inventor's specification as a blueprint for piecing together the prior art to defeat patentability, *i.e.*, the essence of hindsight. *Id.* at 1617. This is why the Federal Circuit placed the burden on the Office to present "clear and **particular" evidence** showing motivation to combine or modify. *Id.* More recently, the Federal Circuit has also held that:

> This factual question of motivation is material to patentability, and could not be resolved on **subjective belief and unknown authority**. It is improper, in determining whether a person of ordinary skill would have been led to this combination of references, simply to '[use] that which the inventor taught against its teacher.' ... Thus the [Office] must not only assure that the requisite findings are made, based on evidence of record, but must also **explain the reasoning** by which the findings are deemed to support the agency's conclusion.

In re Lee, 277 F.3d 1338, 1433, citations omitted, emphasis added (Fed. Cir. 2002).

Applicants submit that the evidence relied upon by the Office for showing motivation to combine *Maubru*, *Bergmann*, and *Dubief-B*, with a liquid fatty alcohol of *Critchley* to obtain the claimed invention is apparently based only on subjective belief or unknown authority. As in *Lee*, beyond the conclusory statements of record, the Office in the outstanding Office Action fails to explain the reasoning supporting the conclusion that one of ordinary skill in the art would have been motivated to use the liquid fatty alcohol emollients of *Critchley*, in combination with *Maubru*, *Bergmann*, and *Dubief-B*, with the expectation of successfully producing a liquid cosmetic composition, comprising, in a cosmetically acceptable medium, at least one liquid fatty alcohol, at least one ceramide compound, and at least one cationic

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surfactant. In fact, Applicants submit that nothing in *Critchley* would have led one of ordinary skill in the art to select as an emollient a liquid fatty alcohol over the other solid fatty alcohol and non-alcoholic emollients disclosed in the reference.

The Office has failed to present "clear and **particular**" **evidence** showing motivation to combine or modify as is required in *Dembiczak*, nor has the Office provided a **reasoned explanation** as required in *Lee*. Thus, the evidence relied upon by the Office does not provide the requisite motivation for one of ordinary skill in the art to devise the Office's proposed combination of *Maubru*, *Bergmann*, *Dubief-B*, and *Critchley*.

Applicants respectfully request reconsideration and withdrawal of the rejection.

VI. Obviousness-Type Double Patenting Rejection

The Office rejected claims 19-81 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-28 of *Maubru* in view of *Bergmann*, *Dubief-B*, and *Critchley* for the reasons set forth on pages 8-10 of the Office Action. Applicants respectfully traverse the rejection.

As discussed above, Applicants submit that there is no motivation to combine *Maubru*, *Bergmann*, and *Dubief-B*, with a liquid fatty alcohol of *Critchley* to obtain the claimed invention. Applicants' above arguments traversing the obviousness rejection over *Maubru* in view of *Bergmann*, *Dubief-B*, and *Critchley* are incorporated herein by reference, and are applied to this double-patenting rejection of claims 19-81. The Office provides no additional evidence that the references, either alone or in combination, provide motivation to one of ordinary skill in the art to use the liquid fatty alcohol of *Critchley*, in combination with *Maubru*, *Bergmann*, and *Dubief-*

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B, with the expectation of successfully producing a liquid cosmetic composition, comprising, in a cosmetically acceptable medium, at least one liquid fatty alcohol, at least one ceramide compound, and at least one cationic surfactant.

Applicants respectfully request reconsideration and withdrawal of the rejection.

SUMMARY

In view of the above amendments and remarks, Applicants submit that this application is in condition for allowance. An early and favorable action is earnestly solicited.

Please grant any extensions of time required to enter this amendment and response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.

Dated: January 17, 2003

By: _____

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APPENDIX

AMENDMENTS SHOWN

In the Claims:

30. (Amended) The composition according to claim 19, wherein said at least one liquid fatty alcohol is chosen from lauryl alcohol, **[myristyl alcohol,]** isomyristyl alcohol, isostearyl alcohol, isocetyl alcohol, isoarachidyl alcohol, 2-octyldodecanol, 2-butyloctanol and oleyl alcohol.

54. (Amended) The composition according to claim 19, further comprising at least one additive chosen from thickeners, perfumes, pearlescent agents, surfactants, preservatives, sunscreens, silicones, anionic polymers, nonionic polymers, cationic polymers, amphoteric polymers, proteins, protein hydrolysates, fatty acids, fatty alcohols, **fatty esters,** hydroxy acids, vitamins, provitamins, panthenol, vegetable oils, animal oils, mineral oils, and synthetic oils.

55. (Amended) The composition according to claim 54, wherein said at least one additive is a C_{16}-C_{40} fatty acid chosen from 18-methyleicosanoic acid**[, hydroxy acids, vitamins, panthenol and fatty esters]**.

61. (Amended) The method according to claim 57, wherein said at least one liquid fatty alcohol is chosen from lauryl alcohol, **[myristyl alcohol,]** isomyristyl alcohol, isostearyl alcohol, isocetyl alcohol, isoarachidyl alcohol, 2-octyldodecanol, 2-butyloctanol and oleyl alcohol.

69. (Amended) The method according to claim 64, wherein said at least one liquid fatty alcohol is chosen from lauryl alcohol, **[myristyl alcohol,]** isomyristyl

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alcohol, isostearyl alcohol, isocetyl alcohol, isoarachidyl alcohol, 2-octyldodecanol, 2-butyloctanol and oleyl alcohol.

79. (Amended) The method according to claim 74, wherein said at least one liquid fatty alcohol is chosen from lauryl alcohol, **[myristyl alcohol,]** isomyristyl alcohol, isostearyl alcohol, isocetyl alcohol, isoarachidyl alcohol, 2-octyldodecanol, 2-butyloctanol and oleyl alcohol.

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Product Number:**68824**

Product Name:**Cetyl alcohol**

Product Information
Description
Certificate of Analysis
MSDS
Options
Print Preview
Bulk Quote
Ask A Scientist

Synonyms: 1-Hexadecanol
Palmityl alcohol
MDL number: MFCD00004760
Molecular Formula: $C_{16}H_{34}O$
Molecular Weight: 242.4
CAS Number: 36653-82-4
Purity Grade: puriss. p.a.
Assay: ≥99.5% (GC)
EC Number: 2531490
BRN: 1748475
Merck Index: *Merck* **13**, 2037
Beilstein Index: *Beil.*1,IV,1876
R&S: : R: 36/37/38, S: 22-24/25

Comments:
puriss. p.a., standard for GC, ≥99.5% (GC)
Shelf life (limited shelf life, expiry date on the label)

Extended specifications	
bp	190 °C/15 mm Hg (lit.)
mp	49-50 °C

Product Number:**74723**

Product Name:**1-Octadecanol**

Product Information
Description
Certificate of Analysis
MSDS
FT-NMR
FT-IR Condensed Phase
Structure Image

Options
Print Preview
Bulk Quote
Ask A Scientist

Synonyms: Octadecyl alcohol
Stearyl alcohol
MDL number: MFCD00002823
Molecular Formula: $C_{18}H_{38}O$
Molecular Weight: 270.5
CAS Number: 112-92-5
MDL Number: MFCD00002823
Assay: ≥99.5% (GC)
EC Number: 2040176
BRN: 1362907
Merck Index: *Merck*13,8883
Beilstein Index: *Beil.*1,IV,1888
R&S: : R: 36/37/38, S: 26-36

Comments:
Selectophore®, ≥99.5% (GC)

Extended specifications	
mp	57-58 °C

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